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January 3, 2018

***VIA ECF AND EMAIL***

The Honorable Joan N. Ericksen  
District Judge, District of Minnesota  
United States District Court  
12W U.S. Courthouse  
300 South Fourth Street  
Minneapolis, MN 55415

RE: *In re Bair Hugger Forced Air Warming Devices Products Liability Litigation*  
MDL No. 15-2666-JNE-FLN

Dear Judge Ericksen:

I write to address a point that the Court identifies in its December 13, 2017 Order as a concession by Defendants. Discussing Dr. Samet's general causation opinion, the Court states: "Defendants apparently concede that, once admitted, Elghobashi's testimony is sufficient to support Samet's causal inference." (Order at 9.)

With respect, Defendants did not concede this point, and in fact argued the contrary. Our reading of the Court's Order is that the "concession" did not determine the outcome of Defendants' motions, however, and therefore this is not a request for reconsideration. We nevertheless write out of an abundance of caution, given the importance of the issue.

On page 24 of Defendants' Medical Experts Memorandum (cited by the Court), Defendants noted merely that Samet and Jarvis rely on Elghobashi's CFD computer model for a "causal *mechanism*" for surgical site infections. This is not the same as saying that the CFD provided a scientifically valid basis for making a causal inference. At the hearing, Defendants argued that Elghobashi's CFD does not provide such a scientifically valid basis. (10/24/17 Tr. at 12:14–13:1, 45:1-9, 70:2-11; 10/26/17 Tr. at 78:9-21.) Defendants cited the *Reference Manual on Scientific Evidence*, which notes that an epidemiological association is necessary for an expert to infer medical causation; without an association, other types of evidence are insufficient to support such an inference. *Reference Manual on Scientific Evidence* 221, 598–99 (3d ed. 2011). The authors caution that some experts "attempted to use these guidelines to support the existence of causation in the absence of any epidemiologic studies finding an association. There may be some logic to that effort, but it does not reflect accepted epidemiologic methodology." *Id.* at 599 n.141 (internal citations omitted).

Defendants also cited case authority concluding that mechanistic plausibility is insufficient to support an inference of causation. *See, e.g., In re Zolof (Sertraline Hydrochloride) Prods. Liab.*

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*Litig.*, 176 F. Supp. 3d 483, 498–99 (E.D. Pa. 2016) (“Without admissible expert testimony based on the epidemiological evidence, Plaintiffs instead have cobbled together evidence of biological plausibility, specific causation opinions based on an assumption that general causation has been established, and anecdotal evidence. Taken together, Plaintiffs’ potentially admissible evidence supports no more than an association between Zolof and certain birth defects . . . . Causation must be based upon more than a possibility.”), *aff’d*, 858 F.3d 787 (3d Cir. 2017).

In sum, Defendants did not concede that Elghobashi’s CFD, once admitted, would be sufficient to support Samet’s causal inference.

Respectfully submitted,

/s/ Benjamin W. Hulse

Benjamin W. Hulse

cc: Hon. William H. Leary III (by email)  
Hon. Franklin L. Noel (by email)